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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,175	07/29/2005	Gary R. Ostroff	2732.1047-010	6462

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,175	OSTROFF ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10, 16-20* is/are pending in the application.

4a) Of the above claim(s) *10 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 19-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 12, 2009 has been entered.

Claims 11-15 have been canceled, and claims 10, and 16-18 remain withdrawn for pertaining to the non-elected species. New claims 19 and 20 have been added, thus claims 1-9 and 19-20 are pending examination on the merits.

Applicant has submitted an information disclosure statement (IDS) on February 12, 2009. Several references were provided in only Chinese and those references were not considered and marked through. Only the English portions of the references provided were considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, claims administration of insoluble whole glucan particles and "at least one complement activating anti-tumor antibody" which applicant has described as being antibodies directed to the tumor or tumor antigens that are able to activate one or more members of the complement cascade (page 19 of specification, lines 25-30). Applicant has not however shown what antibodies would be considered complement activating antibodies nor have they shown how one of skill in the art would determine which antibodies are encompassed by the claims. Furthermore, one would expect for different tumors that different antibodies would be complement activating for some tumors and not others and applicant has provided no direction or explanation how one of skill in the art would determine this, thus one would not know what compounds are actually encompassed by the claims and thus claim 1, and claims 2-9 which depend from claim 1, are rejected for a lack of written description.

Claims 1-9, and 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of tumors or reductions of tumors, does not reasonably provide enablement for suppressing or eliminating them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has successfully argued that the claims are enabling for being effective at treating tumor cells, with treating being reducing tumor size. However the claims are not merely directed towards reducing tumor size as the term "suppressing" encompasses prevention of the tumor cells from appearing and the term "eliminating" encompasses a cure for cancer by eliminating all of the tumor. Neither of these are known in the art as achievable, and there is sufficient reason to doubt that applicant has been able to achieve this with their method. Furthermore, one of skill in the art would not be able to use the method as claimed to eliminate tumors. Additionally, while a compound may be effective at reducing tumors it would not be considered by one of skill in the art to likely be as effective against some tumors versus others and would not be effective enough against all tumors to eliminate or suppress any tumor from appearing. The amount of direction towards elimination or suppression of the tumor cells is minimal and there would be an undue burden of experimentation for one of skill in the art to determine how to use this method as claimed. The breadth of the claims is large do to the large number of different types of tumors encompassed by the claimed.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those

in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, Applicant claims “whole glucan” which is unclear what applicant is claiming as glucan is a polymer with specific linkages and can vary greatly in molecular weight. Therefore the term “whole” is unclear because there isn’t a single defined size to glucan and yet the term “whole” implies that there is, under that analysis only the largest known glucan would be considered “whole” and anything less would be a fragment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheung et al. (US 7,462,607) in view of Suzuki et al. (Gann, 1969, Vol. 60, No. 3, pages 273-237 – abstract only).

In claim 1, applicant claims a method of suppressing or eliminating tumor cells, comprising administering insoluble whole glucan particles and at least one anti-tumor antibody to a subject in need of suppressing or eliminating tumor cells. Applicant has elected trastuzumab as the antibody and thus claim 1-3 read upon a combination therapy of trastuzumab and insoluble whole glucan. Chung et al. teach a treatment for cancer that comprises of β-glucan and antibodies (abstract). They teach treatment with an effective amount of glucan to enhance the efficacy of antibodies (column 7, lines 35-37). They do not teach the specific antibody elected by applicant, trastuzumab, however they do teach rituximab (column 7, lines 52-56) which is also claimed in claim 3. Thus they teach treatment of patients with cancer, which would be in need of suppressing or eliminating tumor cells and they teach treatment with both glucan and an

anti-tumor antibody. They do not specify if glucan is whole or insoluble, however naturally found glucan is insoluble and Suzuki et al. teaches that insoluble glucan is more effective as an anti-cancer agent than soluble glucan (abstract) and thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use insoluble glucan. As discussed above, it is not clear what applicant intends to claim by "whole glucan" as it is a polysaccharide that varies in molecular weight by the number of linkages. However Cheung et al. teach that the glucan is of high molecular weight (column 3, lines 1-15) and thus one of ordinary skill in the art would consider this to include a "whole" glucan. Thus claim 1 is unpatentable over Cheung et al. in view of Suzuki et al.

In claim 2, applicant claims that the antibody is introduced via direct administration of a monoclonal antibody or polyclonal antibody. Cheung et al. teaches monoclonal antibodies (column 7, lines 38-44) and direct administration of the antibody (column 7, lines 44-47) and thus claim 2 is also unpatentable over Cheung et al. in view of Suzuki et al.

In claim 4 applicant claims the glucan and antibody provide a synergistic effect. This is an effect of the method of claim 1 and therefore administering the same method would have the same effect. Additionally, Cheung et al. teaches that the glucan enhances the efficacy of the antibodies which is a synergistic effect. They even teach that there was a remarkable synergistic effect (column 14, lines 39-45). Thus claim 4 is also unpatentable over Cheung et al. in view of Suzuki et al.

In claim 5 applicant claims the glucan is administered orally, and in claim 6 applicant claims parenteral administration. Cheung et al. teaches oral administration of glucan (column 14, lines 1-19) and also teaches that intravenous (parenteral) administration of glucan is known in the art (column 14, lines 29-33) and while it is not the preferred embodiments of Cheung et al. it would be obvious to one of ordinary skill in the art at the time of the invention that intravenous administration would also be an option for administration. Thus claims 5 and 6 are unpatentable over Cheung et al. in view of Suzuki et al.

In claim 7 applicant claims the glucan particle is derived from yeast. Cheung et al. teach that glucan can be extracted from yeast (column 1, lines 57-60). Thus claim 7 is unpatentable over Cheung et al. in view of Suzuki et al.

In claims 8-9 applicant claims that the glucan is derived from a plant source, specifically barley. Cheung et al. teaches glucan derived from barley (abstract) and thus claims 8-9 are unpatentable over Cheung et al. in view of Suzuki et al.

Claims 3 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheung et al. (US 7,462,607) in view of Suzuki et al. (Gann, 1969, Vol. 60, No. 3, pages 273-237 – abstract only), in further view of Leyland-Jones et al. (The Lancet Oncology, already of record in the office action mailed August 7, 2008).

In claims 3 and 19-20, applicant claims the method administering insoluble whole glucan and an antibody to a subject in need of suppressing or eliminating tumor cells and in claims 3 and 19-20 applicant specifies that the antibody is trastuzumab which is

not taught by Cheung et al. However, as discussed in the previous office action mailed August 7, 2008, Leyland-Jones et al. teaches use of trastuzumab for treatment of cancer (abstract) including specifically treatment of breast cancer (abstract). Cheung et al. includes antibodies for breast cancer (column 1, lines 16-25). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention that the method of Cheung et al. could also be used with an antibody known to be effective for treatment of cancer. As discussed in the previous office action, it is obvious to combine two treatments known to be effective for treatment of the same disease. Thus claims 3 and 19-20 are unpatentable over Cheung et al. in view of Suzuki et al. in further view of Leyland-Jones et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/

Examiner, Art Unit 1614